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Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

July 1, 2008

TO: INTERESTED PARTIES

SUBJECT: EXEMPTION TO HEALTH AND SAFETY CODE SECTION 124172
(MERCURY-CONTAINING VACCINES) FOR JAPANESE
ENCEPHALITIS VIRUS VACCINE INACTIVATED, 2008-2009

In 2004, in order to ensure that pregnant women and children under age three years have access to mercury-free vaccines, Governor Schwarzenegger signed AB 2943 (Pavley, Chapter 837, Statutes of 2004). Effective July 1, 2006, under the terms of AB 2943, vaccines containing levels of mercury greater than specified limits cannot be administered to pregnant women and young children, except under certain circumstances.

While commonly used vaccines administered in the United States are available in mercury-free formulations, the less frequently used Japanese Encephalitis vaccine is not. Japanese Encephalitis, a mosquito-borne infection, is the leading cause of viral encephalitis (brain infection) in Asia and parts of Oceania. Since 2005, major outbreaks of Japanese Encephalitis have resulted in illness and death of thousands of persons in India and Nepal. Most persons with encephalitis caused by the Japanese Encephalitis virus either die or have residual neurologic disease. Unimmunized children in affected areas are at highest risk of Japanese Encephalitis, while infection during pregnancy may cause miscarriage. There is currently no treatment for Japanese Encephalitis. Each year, approximately 4,300 Californians (excluding military) one year of age and older, traveling for a month or longer in Asia or Oceania, receive the Japanese Encephalitis vaccine in accordance with national medical and public health recommendations.

The U.S. Food and Drug Administration (FDA) has licensed only one vaccine against Japanese Encephalitis for use in the United States. The formal name of the vaccine is Japanese Encephalitis Virus Vaccine Inactivated, and its trade name is JE-VAX®. It is manufactured in Japan by the Research Foundation for Microbial Diseases of Osaka

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University ("BIKEN®") and distributed in the United States by Sanofi Pasteur, Inc.

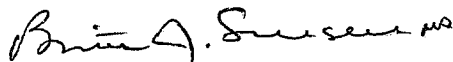
Given the continuing absence of mercury-free Japanese Encephalitis vaccine and the risk of fatal disease or brain injury from Japanese Encephalitis, Health and Human Services Agency Secretary Kimberly Belshé has exercised the authority provided by AB 2943, with concurrence from Governor Schwarzenegger, and granted an exemption from California Health and Safety Code, Section 124172 (a), for Japanese Encephalitis Virus Vaccine Inactivated for another year from July 1, 2008 to June 30, 2009. Previous 12-month exemptions for Japanese Encephalitis vaccine have been granted since July 2006 under the same authority for the same reasons. This exemption will allow the Japanese Encephalitis vaccine to be administered to children younger than three years old and pregnant women to protect against severe illness or death should they visit affected areas for extended periods of time.


Secretary Belshé and Governor Schwarzenegger have granted this exemption because of the health risk posed by Japanese Encephalitis virus to those residing or traveling in affected areas, and because there is no alternative vaccine for Californians seeking protection against Japanese Encephalitis.

Governor Schwarzenegger and Secretary Belshé remain deeply committed to implementing AB 2943 and ensuring that pregnant women and young children have access to mercury-free vaccines whenever possible.

If you have any questions, please contact the California Department of Public Health, Immunization Branch, at (510) 620-3737.

Sincerely,



 Mark B Horton, MD, MSPH
Director